UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CAROL LEWIS, Plaintiff, v. SYLVIA MATHEWS BURWELL Secretary of the Department of Health and Human Services, Defendant.	)	Civil Action No.: 1:15-CV-13530-NMG

DEFENDANT'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS

Defendant Secretary of the Department of Health and Human Services ("the Secretary" or "Defendant") requests that the Complaint be dismissed pursuant to Rule 12(b)(1) and (6), Federal Rules of Civil Procedure, for the reasons set forth below.

I. PRELIMINARY STATEMENT

In Counts I through VII of her Complaint, Plaintiff requests that this Court set aside the Secretary's decision to deny Plaintiff's request for Medicare coverage for her continuous glucose monitor and its related supplies pursuant to the Administrative Procedures Act and set aside the agency's general determinations prohibiting such coverage, because the Secretary's decision is contrary to law, arbitrary, capricious, and unsupported by substantial evidence. In Count VIII, Plaintiff requests that this Court issue a writ of mandamus compelling the Secretary to issue administrative decisions in a timely fashion. The Secretary respectfully requests that this Court dismiss the Complaint for lack of jurisdiction and, as to Count VIII, for failure to state a claim upon which relief can be granted.

I. STATEMENT OF FACTS AND PRIOR ADMINISTRATIVE PROCEEDINGS

Plaintiff, a Medicare Part B beneficiary residing in Chatham, Massachusetts, is a Type 1 diabetic who, pursuant to her physician's prescription, uses a continuous glucose monitor to assist in the management of her diabetes. Compl. ¶ 17, 80-83. Plaintiff requested Medicare Part B coverage for her continuous glucose monitor and its related supplies. Compl. ¶ 85. CMS' contractor denied Plaintiff's request for coverage and Plaintiff subsequently sought redetermination and reconsideration and received unfavorable decisions at both levels of review. Compl. ¶ 86. Plaintiff appealed the reconsideration decision to an Administrative Law Judge ("ALJ") at the Office of Medicare Hearings and Appeals ("OMHA") who issued an unfavorable decision and to the Medicare Appeals Council ("MAC") which affirmed the ALJ's decision. Compl. ¶ 88, 93-94, 101. Plaintiff then filed this Complaint in Federal district court, alleging that the Secretary's denial of Medicare coverage violated the APA as it was contrary to law, arbitrary, capricious, and unsupported by substantial evidence and that the Secretary should be compelled to issue her administrative decisions in a timely manner. Compl. ¶ 105–132.

In December 2014, at the same time that Plaintiff was pursuing the appeal detailed above, Plaintiff filed a separate complaint with an ALJ at the Departmental Appeals Board ("DAB") pursuant to 42 U.S.C. § 1395ff(f)(2). Compl. ¶ 95; *In Re: LCD Complaint: Glucose Monitors (L11530) (Carol Lewis)*, DAB Docket No. C-15-1021. In this administrative proceeding, Plaintiff's challenged the reasonableness of Local Coverage Determination ("LCD") L27231 and Local Coverage Article ("LCA") A33614, arguing that the continuous glucose monitor was medically necessary for her and the provisions in the LCD and LCA that precluded coverage

were invalid when evaluated under the reasonableness standard. Compl. ¶ 95. Plaintiff's case is currently pending with an ALJ.[1]

II. STATUTORY AND REGULATORY FRAMEWORK

A. Medicare Act

1. Medicare Statute

Enacted in 1965, the Medicare program pays for covered medical care provided to eligible aged and disabled individuals. 42 U.S.C. § 1395 *et seq.* To be "covered," the medical care must satisfy certain basic requirements: it must fall within a defined item or service category, be "reasonable and necessary". 42 U.S.C. § 1395y(a)(1)(A). The Act "precludes reimbursement for any 'items or services . . . which are not reasonable and necessary for the diagnosis or treatment of illness or injury.'" *Heckler v. Ringer*, 466 U.S. 602, 605 (1984).

Original "fee-for-service" Medicare consists of two basic parts. Part A of Medicare, 42 U.S.C. § 1395c *et seq.*, provides for the payment of inpatient hospital and related post-hospital benefits on behalf of eligible individuals. Part B of Medicare, 42 U.S.C. § 1395j *et seq.*, establishes a voluntary supplemental insurance program intended for the payment of certain other health services. *See* 42 U.S.C. 1395k.

In enacting the Medicare statute, Congress provided substantial authority to the Secretary (who acts through the Centers for Medicare & Medicaid Services ("CMS")) to administer the program and prescribe regulations necessary to implement and effectuate the Medicare statute. 42 U.S.C. § 1395hh(a)(1). The Medicare statute permits the Secretary to contract with private

[1] In ¶ 95 of the Complaint, Plaintiff alleges that the ALJ concluded that the LCA provisions stating that continuous glucose monitors were precautionary were not supported by the LCD record; however, the ALJ has yet to issue a final ruling on the validity of the LCD and LCA. Compl. ¶ 97. The ALJ conducted a prehearing conference with the parties on December 3, 2015, and ordered the Medicare Administrative Contractor and Plaintiff to submit a pre-hearing briefs; Plaintiff's pre-hearing brief is due on February 16, 2016.

entities, known as Medicare Administrative Contractors, to administer the Medicare program. 42 U.S.C. § 1395kk-1. The Medicare Administrative Contractors are responsible for making coverage determinations, issuing payments, and developing LCDs that identify whether or not a particular item or service is covered on a Medicare Administrative Contractor-wide basis in accordance with the reasonableness provisions outlined in 42 U.S.C. 1395y(a)(1). *See* 42 U.S.C. §§ 1395kk-1(a)(4), 1395ff(f)(2)(B), 1395kk-1 note.

Pursuant to this delegation of authority, NHIC, Corp., a Medicare Administrative Contractor responsible for making local coverage determinations in certain geographical areas including Massachusetts, issued LCD L11530 which outlined when home glucose monitors and related supplies may be covered by Medicare. *See* Local Coverage Determination (LCD) for Glucose Monitors (L11530) (as amended in 2014). In the text of LCD L11530, reference is made to LCA A33614, a related local coverage document that states, "[c]ontinuous glucose monitors are considered precautionary and therefore non-covered under the DME benefit." *See* Local Coverage Article for Glucose Monitors – Policy Article (A33614) (as amended in 2014).

The determination that CGMs are "precautionary" means that Medicare does not cover the cost of CGMs because CGMs do not fall within a defined Medicare benefit category. In order to receive payment under Medicare Part B, the Medicare beneficiary must demonstrate that a service or item: (1) falls within a defined Medicare benefit category (as outlined in 42 U.S.C. § 1395k); and (2) is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (as outlined in 42 U.S.C. § 1395y). Here, Plaintiff may argue that CGMs fall into the defined Medicare benefit category of "durable medical equipment." *See* 42 U.S.C. § 1395k(a)(2)(G), referencing 42 U.S.C. § 1395m(a)(13);however, CMS′ Medicare Benefit Policy Manual ("MBPM"), provides that

"durable medical equipment" is equipment that can withstand repeated use, is primarily and customarily used to serve a medical purpose, generally not useful in the absence of an illness or injury, and appropriate for use in the home. MBPM, Ch. 15, § 110.1. ". . . [F]irst-aid or precautionary-type equipment (such as preset portable oxygen units) . . . is . . . nonmedical in nature" and is therefore not durable medical equipment. MBPM, Ch. 15 § 110.1(B)(2).

2. The Administrative Review Process

a. Administrative Review of Individual Medicare Claims

CMS, through its Medicare Administrative Contractors, processes millions of Medicare claims each year; to ensure efficiency and economy, it has developed a multi-level administrative claims and appeals process that must be exhausted before a Medicare beneficiary may seek judicial review. *See Heckler v. Ringer*, 466 U.S. 602, 627 (1984); 42 U.S.C. § 1395kk-1. As the statutory and regulatory framework establishes, a Medicare beneficiary who seeks to challenge a denial of coverage must first request a redetermination of the denial by a Medicare contractor. 42 U.S.C. § 13955ff(a)(3)(B)(i); 42 C.F.R. §§ 405.904(a)(2), 405.948. Next, the beneficiary may request reconsideration by a qualified independent contractor ("QIC"). 42 U.S.C. §§ 1395ff(c)(1), (2); 42 C.F.R. § 405.960. After reconsideration, the beneficiary may request a hearing before an ALJ at HHS' Office of Medicare Hearings and Appeals. *See* 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 405.1002. Last, the beneficiary may request that the MAC review the ALJ's decision (or, alternatively, the MAC may elect on its own motion to review the ALJ's decision). 42 C.F.R. §§ 405.1100, 405.1110. The MAC has the authority to adopt, modify, or reverse the ALJ's decision. 42 C.F.R. § 405.1128. The MAC's decision is final and binding on all parties unless it reopens its decision in accordance with § 405.980 or a Federal district court issues a modifying decision. 42 C.F.R. § 405.1130. A party may file an action in Federal district

court within 60 calendar days after receipt of the MAC's decision or, if the MAC fails to timely issue a decision, after the MAC's applicable adjudication period expires. 42 C.F.R. §§ 405.1100, 405.1136.

b. Administrative Review of Local Coverage Determinations

In addition to seeking administrative review of individual Medicare claims, as described above, Medicare beneficiaries who meet the definition of an aggrieved party[2] are permitted to file complaints challenging local coverage determinations. 42 U.S.C. § 1395ff(f)(2)(B), 42 C.F.R. § 426.400. The complaints are adjudicated by an ALJ at the DAB's Civil Remedies Division who reviews the record that the Medicare Administrative Contractor submits to support its LCD. 42 U.S.C. § 1395ff(f)(2)(A)(i). If the ALJ determines that the record is incomplete or lacks adequate information to support the validity of the LCD, the ALJ may hold a hearing and/or consult with scientific and clinical experts to evaluate the reasonableness of the LCD but the ALJ must defer to the reasonable findings of fact and interpretations of law made by the Secretary. 42 U.S.C. § 1395ff(f)(2)(A); 42 C.F.R. § 426.405.

After the ALJ issues her decision, either the aggrieved party or the Secretary may request that the Departmental Appeals Board's ("DAB's") Appellate Division review the decision. 42 U.S.C. § 1395ff(f)(2)(A)(ii); 42 C.F.R. § 426.465. If the DAB determines that the LCD is valid, neither the Medicare Administrative Contractor nor CMS is required to take any action; however, if the DAB determines that the LCD is invalid, then the Medicare Administrative Contractor must reopen the aggrieved party's claim and adjudicate any future claims for the same service without reference to the invalidated LCD provisions. 42 C.F.R. §§ 426.488,

[2] An individual is an aggrieved party if she is "entitled to Medicare benefits under part A . . . or enrolled under Part B . . . or both, who are in need of the items or services that are the subject of the coverage determination." 42 U.S.C. § 1395ff(f)(5); 42 C.F.R. § 426.400(c)(5).

426.460(b). The DAB's decision constitutes final agency action and is subject to judicial review. 42 U.S.C. § 1395ff(f)(2)(A)(iv); 42 C.F.R. § 426.490.

3. Federal District Court Review of Final Agency Action

After the MAC or the DAB issues its decision or fails to meet the statutory and regulatory timeframes prescribed for issuing its decision, an individual is permitted to file suit in Federal district court. See 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A), 1395ff(f)(2)(A); 42 C.F.R. §§ 405.1130, 405.1136. The Federal district court shall then ". . . have the power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the [Secretary], with or without remanding the case for a rehearing." 42 U.S.C. § 405(g), *incorporated into Medicare statute by* 42 U.S.C. § 1395ff(b)(1)(A).

B. <u>Administrative Procedures Act</u>

The Administrative Procedures Act ("APA") permits an individual who has suffered legal wrong because of agency action to seek judicial review of the action. 5 U.S.C. § 702. However, in order for a Federal district court to exercise jurisdiction, the agency action must be final and the individual must not have any other adequate remedy. 5 U.S.C. § 704. If these conditions are met, the court may:

> (1) compel agency action unlawfully withheld or unreasonably delayed; and (2) hold unlawful and set aside agency action, findings, and conclusions found to be—(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (D) without observance of procedure required by law; (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

5 U.S.C. § 706.

C. Mandamus Act

The Mandamus Act vests Federal district courts with "original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff." 28 U.S.C. § 1361. Relief under the Mandamus Act is limited to instances where a plaintiff demonstrates that he has exhausted all other avenues of relief and only if the defendant owes him a "clear nondiscretionary duty." *Heckler v. Ringer*, 466 U.S. at 616.

III. THE COMPLAINT IS REQUIRED TO BE DISMISSED.

The Complaint is required to be dismissed because Plaintiff's challenge to the HHS' contractor's LCD and LCA has not been exhausted through the administrative process, because judicial review of HHS' denial of Plaintiff's claims for reimbursement are not available under the Administrative Procedure Act, and because mandamus relief is available only under exceptional circumstances of clear illegality, not present here.

A. Counts IV, V, and VI of the Complaint Should be Dismissed Because Relief is Requested for Agency Action That Is Not Ripe For Judicial Review

Counts IV through VI of the Complaint are required to be dismissed pursuant to Rule 12(b)(1), Federal Rules of Civil Procedure, for lack of subject matter jurisdiction because there is no final agency action on the challenges raised to the applicable HHS contractor's LCD and LCA – policies that deny Medicare coverage for CGM's --, and, accordingly, the issues are not ripe for judicial review.

Counts IV through VI of the Complaint request that the Secretary's interpretation of, application of, and deference to CDL L27231 and LCA A33614 be set aside as arbitrary, capricious, and unsupported by substantial evidence. Plaintiff has raised these challenges at the

administrative level, through the agency's established administrative process, and there is no final agency action on these challenges.

In December 2014, Plaintiff submitted a formal complaint to the DAB challenging the provisions of LCD L11530 and LCA A33614. Compl. ¶ 95. Plaintiff took the position that the provisions of the LCD and LCA were invalid because they failed to conform to opinions expressed in scientific and medical literature, were contrary to NCD 40.2, and conflicted with other Medicare policy concerning reasonableness and medical necessity. The administrative complaint was assigned to an ALJ, who concluded that he had jurisdiction over the complaint and ordered the parties to develop the record.[3] The parties are currently in the process of preparing for formal hearing and filing prehearing pleadings. Final agency action in this context is the DAB's decision after appeal from an adverse ALJ's decision, *see* 42 C.F.R. § 426.490, which has not occurred because Plaintiff's claims regarding the LCDs and LCAs are only pending with the ALJ. *See Conservation Law Foundation, Inc. v. Jackson*, 964 F. Supp. 2d 152, 165-166 (D. Mass. 2013) (Under the APA, final agency action exists only where (1) the agency action marks the consummation of the agency's decision-making process and (2) the agency action is one in which rights or obligations have been determined or from which legal consequences will flow).

In *Heckler v. Ringer*, plaintiffs challenged Medicare's policy of not paying benefits for a certain kind of surgery. 466 U.S. at 604-605. The Court construed these challenges as arising under the Medicare Act, and, accordingly, subject to review pursuant to 42 U.S.C. 1395ff(b)(1)(A) and 42 U.S.C. § 405(g), requiring exhaustion through Medicare administrative procedures.

[3] The Secretary reserves the right to contest the ALJ's determination that he has jurisdiction.

In evaluating whether Plaintiff's arguments challenging government action are ripe, the court must consider: (1) "whether the issue presented is fit for review[,] [t]his branch of the test typically involves subsidiary queries concerning finality, definiteness, and the extent to which resolution of the challenge depends upon facts that may not yet be sufficiently developed," and (2) ". . .the extent to which hardship looms—an inquiry that typically turns upon whether the challenged action creates a direct and immediate dilemma for the parties." *Id*. at 535. "The notion that disputes which turn on purely legal questions are always ripe for judicial review is a myth." *Id*. at 537. Plaintiff's challenges to the LCDs and LCAs Medicare's policies Plaintiff's challenges to the rules are not ripe for judicial review. *Ernst & Young v. Depositors Economic Protection Corp.*, 45 F.3d 530, 534 (1st Cir. 1995) (a district court may conclude that it lacks subject matter jurisdiction under Rule 12(b)(1) if it is presented with a case that has not been exhausted through administrative procedures).

Plaintiff's challenges to LCD claims are not ripe for review because the facts regarding her challenge to LCD L11530 and LCA A33614 are under development and consideration at the agency level, the ALJ has yet to issue his decision, and, when the ALJ issues his decision, it is subject to review by the DAB before becoming a final agency action.

There is no basis for Plaintiff's evident desire to bypass administrative procedures here. Any inconvenience that she may experience from lack of reimbursement for the CGM's while she pursues the required administrative remedies applicable to her challenge to the LCDs and LCAs, is insufficient to permit her to bypass the statutory administrative review process. 42 U.S.C. § 1395ff(f)(2). In *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1,13 (2000), the Supreme Court acknowledged that the requirement that channeling virtually every legal attack arising under the Medicare statute through administrative procedures may create

"occasional individual, delay-related hardship." It reasoned, however, that "[i]n the context of a massive, complex health and safety program such as Medicare, embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations, any of which may become the subject of a legal challenge in any of several different courts, paying this price may seem justified." *Id.* at 13. Plaintiff points to no compelling reasons for bypassing the statutorily-mandated procedures for developing evidence, argument, and deliberation – for jumping ahead of the line -- and judicial review before completion of that process is unwarranted and precluded by Rule 12(b)(1).

B. Counts I, II, III, IV, V, VI, and VII Should be Dismissed Because the Administrative Procedure Act Does Not Provide Judicial Review of these Claims.

Plaintiff requests that this Court review Counts I through VII pursuant to section 706 of the Administrative Procedure Act, 5 U.S.C. § 706. Pl. Compl. ¶ 105. However, the APA does not provide for judicial review in this action. The APA provides generally for review of final administrative agency actions "for which there is no other adequate remedy in a court." 5 U.S.C. § 704. It provides for review if there are "no special statutory review proceedings applicable." 5 U.S.C. § 703. "[J]urisdiction under the APA is precluded "if there is a more specific provision for review." *Conservation Law Foundation, Inc. v. Busey*, 79 F.3d 1250, 1257 (1st Cir. 1996). *See* 5 U.S.C. § 703 ("Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review."). *See Japan Whaling Ass'n v. Am. Cetacean Society*, 478 U.S. 221, 230 n. 4 (1986).

This Court lacks jurisdiction under the APA to review HHS' decisions because judicial review is available through other, specific statutory provisions. As noted, claims arising under the Medicare Act are not reviewable under the APA because other statutory review is provided under the Medicare Act. Plaintiff's administrative challenges of HHS' denial of her individual

Medicare claims for reimbursement and of the LCDs and LCAs arise under the Medicare Act only, and she acknowledges that the agency has issued a final decision under the Medicare Act, through the MAC, of her individual claims for reimbursement. 42 U.S.C. § 1395ff(b)(1)(A). Because the challenged agency actions were decided pursuant to the Medicare Act, judicial review of HHS' final decisions under the Medicare statute is limited to the grant of jurisdiction provided by the Medicare Act. 42 U.S.C. § 405(g)-(h) provides for judicial review of decisions by the Commissioner of Social Security, and the Medicare Act adopts this provision as conferring jurisdiction for review of Medicare decisions. 42 U.S.C. § 1395ii, 1395ff(b). *See Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. at 13 (claims where both the standing and substantive basis of the claim is the Medicare Act must be channeled through the agency and judicially reviewed in accordance with section 405(g)-(h)); *see also Puerto Rican Ass'n of Physical Medicine and Rehabilitation, Inc. v. U.S.*, 521 F.3d 46, 48 (1st Cir. 2008) (judicial review under section 405(g), citing *Heckler v. Ringer*, 466 U.S. 602, 615(1975); *Beechwood Restorative Care Center v. Thompson*, 494 F. Supp. 2d 181, 191, 193 (W.D.N.Y. 2007) (same).[4] The review provided under the Medicare Act is whether Medicare's findings are "supported by substantial evidence", such that "a reasonable mind, reviewing the evidence in the record as a whole, could accept it as adequate to support his conclusion." *Rodriquez v. Sec'y of HHS*, 647 F.2d 219, 222 (1st Cir. 1981), citing *Richardson v. Perales*, 402 U.S. 389, 401 (1971). The standard is deferential and ". . . means something less than the weight of the evidence[;]"

[4] Title 42 U.S.C. § 1395ff(b)(i)(A) provides: "Subject to subparagraph (D), any individual dissatisfied with any initial decision under subsection (a)(1) of this section shall be entitled to reconsideration of the determination, and subject to subparagraphs (D) and (E), a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title and, subject to paragraph (2), to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title. For purposes of the preceding sentence, any reference to the "Commissioner of Social Security" . . . shall be considered a reference to the 'Secretary" . . . of the Department of Health and Human Services."

specifically, it requires a court to consider relevant evidence a reasonable mind might accept as adequate to support the conclusion reached but does not permit the court to ". . .substitute [its] own opinion for that of the agency charged with the responsibility of administering the Medicare Program simply because it is possible to draw a different conclusion from the same evidence." *Faulkner Hosp. Corp. v. Schweiker*, 537 F. Supp. 1058, 1063-1064 (D. Mass. 1982). Plaintiff does not seek a "substantial evidence" review under the Medicare Act, but seeks only APA review, and, accordingly, her claims in these counts do not allege a jurisdictional basis for review.

C. Count VIII Should be Dismissed because Plaintiff is Not Entitled To Mandamus Relief.

Plaintiff appears to take the position that this Court should issue a mandamus in her favor regarding her individual claim for CGM reimbursement because HHS failed to timely complete the administrative process. This does not warrant relief under the Mandamus Act. For a court to issue a writ of mandamus, a plaintiff must demonstrate "that he has exhausted all other avenues of relief and only if the defendant owes him a clear, nondiscretionary duty." *Heckler v. Ringer*, 466 U.S. at 616 (in action challenging the Secretary of HHS's policy of not paying Medicare benefits for particular kind of surgery). And "[t]he mandamus remedy is available only under exceptional circumstances of clear illegality." *Cervoni v. Sec'y of Health, Ed. Welfare*, 581 F.2d 1010, 1019 (1st Cir. 1978).

As an initial matter, Plaintiff's requests a mandamus order for HHS' completion of administrative procedures on her individual reimbursement claims, but, in fact, both the ALJ and the MAC have issued their decisions and, accordingly, final agency action has occurred. *Randall Wolcott v. Sebelius*, 635 F.3d 757, 774 (5th Cir. 2011) (holding plaintiff's claim for mandamus to compel removal of plaintiff from prepayment review for Medicare claims was moot because

agency had already done so); *see also Ahmadabadi v. Lambrecht*, 2015 WL 7110796, at *3 (D. Colo. 2015) (holding, "[a] petition for mandamus to compel an agency to act is rendered moot when the agency has taken action granting the relief requested in the mandamus petition.")

Moreover, even if either of those decisions had not occurred and were untimely, Plaintiff would not have been entitled to a mandamus order because she had other adequate remedies available to her. While the Medicare statute and regulations require an ALJ to issue a decision no later than 90 days after receiving a plaintiff's hearing request, both the statute and regulation provide an avenue for relief— first, the right to escalate the matter to the MAC when the ALJ is unable to issue a timely decision. 42 U.S.C. § 1395ff(d)(1),(3); 42 C.F.R. §§ 405.1016(a), 405.1104. The ALJ's decision here took more than the prescribed 90 days, but there was a clear statutory and regulatory procedure for speeding up the final agency decision and Plaintiff took no advantage of it. In addition, while the Medicare statute and regulations require the MAC to issue a decision no later than 90 days after receipt of Plaintiff's request for review of the ALJ decision or 180 days after receipt of Plaintiff's request for escalation from the ALJ to the MAC, both the relevant statute and regulation permit Plaintiff to seek judicial review of her claim if the MAC does not issue a decision within that timeframe. 42 U.S.C. § 1395ff(d)(2),(3), 42 C.F.R. § 405.1100. Plaintiff does not contend that she sought judicial review after the MAC failed to respond or issue a timely decision, as she was permitted to do. *See B & H Medical, LLC v. U.S.*, 116 Fed. Cl. 671, 691 ("In order to obtain federal court review of its claim, [Plaintiff] must first either have received a Medicare Appeals Council (MAC) decision, or have filed for MAC review of an ALJ decision, but received no MAC decision within the applicable adjudication period. 42

C.F.R. § 405.1136(a).").[5] Since Plaintiff had the right to escalate her request to the MAC after the ALJ failed to issue a timely decision and to Federal district court after the MAC failed to issue a timely decision, Plaintiff had an adequate remedy available. She would not have been entitled to a mandamus order during the administrative process, and although the process has been completed and agency action is final, she is not entitled to a mandamus order of any kind based on the agency's slowpoke consideration of her claims. *See Cumberland County Hosp. System, Inc. v. Burwell*, 2015 WL 1249959 at *6 (E.D.N.C. 2015) (holding that the statutory escalation procedures showed that Congress ". . . expressly anticipated delays in Medicare adjudications and prescribed escalation under the remedy;" therefore, mandamus relief is not warranted.); *see also See American Hospital Association v. Burwell*, 76 F. Supp. 3d 43, 56 (D.D.C. 2014) (holding that mandamus was not appropriate where an ALJ's failure to issue timely decisions stemmed from HHS budgetary constraints and completing priorities).

CONCLUSION

For the foregoing reasons, Defendant requests that this Court dismiss the Complaint.

Respectfully submitted,

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[5] With respect to Plaintiff's challenges to the LCD's and LCA's, there is no allegation that HHS's administrative appeal procedures are or were untimely.

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Certificate of Service

I hereby certify that the foregoing will be filed through the electronic filing system of the Court, which system will serve counsel for Plaintiff electronically, on this first day of February 2016.

/s/ Anita Johnson